Supreme Court, U.S.
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No.

In The

Supreme Court of the United States

October Term, 1995

SMITH & NEPHEW DYONICS, INC.,

Petitioner,

vs.

RUSSELL VIOLETTE,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR WRIT OF CERTIORARI

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58 pp

QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act's preemption of state common law claims involving a medical device reviewed by the Food and Drug Administration ("FDA") is jurisdictional in nature because Congress (1) expressly preempted any and all state requirements different from, or in addition to, federal requirements for safety and effectiveness, and (2) vested the FDA with the sole authority to establish federal requirements for safety and effectiveness of medical devices.

RULE 29.6 STATEMENT

Petitioner's parent company is Smith & Nephew Consolidated, Inc. Petitioner has no non-wholly owned subsidiary companies. In October, 1995, petitioner changed its name from Smith & Nephew Dyonics, Inc. to Smith & Nephew Endoscopy, Inc.

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NO. 95-

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SMITH & NEPHEW DYONICS, INC.
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On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

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PETITION FOR WRIT OF CERTIORARI

Petitioner Smith & Nephew Dyonics, Inc. ("Smith & Nephew") hereby petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case. The First Circuit held that preemption under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§301-395 (1994), is non-jurisdictional in nature, and was waived by a defendant who did not raise it substantively until after trial, even though the FDCA grants to the Food and Drug Administration ("FDA") exclusive authority to review the safety and effectiveness of medical devices.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a) is reported at 62 F.3d 8 (1st Cir. 1995). The judgment of the United States District Court for the District of Maine (App. 14a) is not reported. The order of the district court denying defendant's motion for judgment notwithstanding the verdict or for a new trial (App. 15a) is not reported. The district court's amended judgment (App. 17a) is also not reported.

JURISDICTION

The court of appeals entered judgment on August 7, 1995. Smith & Nephew filed a timely petition for rehearing and suggestion for rehearing en banc on August 22, 1995, which the court of appeals denied on November 29, 1995 (App. 18a). This Court has jurisdiction under 28 U.S.C. §1254(1)(1988).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Appendix F (App. 20a) sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. §§360(k), 360c(f)(1), 360c(i), 360k (1994); 21 C.F.R. §§807.81, 807.87, 808.1(d), 888.1100 (1995).

STATEMENT OF THE CASE

Conflicting with previous decisions of this Court, several circuit courts, and with the legislative intent behind the FDCA, specifically the Medical Device Amendments of 1976, the First Circuit held that preemption under the FDCA was non-jurisdictional in nature, and thus waivable by a defendant. This Petition asks the Court to review this matter, which sets forth a question similar to that presented in *Medtronic v. Lohr* which this Court recently granted certiorari, Nos. 95-754 and 95-886, and determine whether FDCA preemption is jurisdictional and deprives courts of the ability to review the safety and efficacy of medical devices.

A. Background and Significance of the Federal Law Question.

In 1976, Congress passed the Medical Device Amendments to the FDCA ("MDA"), 21 U.S.C. §§360 *et seq.* (1994), establishing a comprehensive federal scheme governing the development, approval, and use of medical devices. Pursuant to the authority granted it in the MDA, the FDA promulgated an extensive set of federal regulations defining, in detail, the regulatory process required for a manufacturer to have a medical device approved for marketing and sale in the United States. See 21 C.F.R. §§800.10 *et seq.* (1995). Recognizing the importance of medical devices to the health of the nation, Congress enacted the MDA as "a balanced regulatory proposal" between the public's health and safety on the one hand and the encouragement of innovations in medical technology which would be stifled by unnecessarily strict regulations. H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976).

To ensure that a proper balance between safety and innovation was maintained, Congress granted to the FDA the authority over medical device development, review and approval. Consistent with its grant of authority to the FDA, Congress enacted an express preemption provision in the MDA which reads in part:

> Except as provided in subsection (b) ... no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a) (1994) (App. 24a). Under §360k, the states cannot overrule the decisions of the FDA with respect to the safety or effectiveness of a medical device. *See* H.R. Rep. No. 853, at 45 (stating that §360k was intended as a "general prohibition on non-Federal regulation").[1]

Pursuant to its mandate from Congress, the FDA established an extensive set of regulations governing the safety and effectiveness of medical devices. The MDA categorizes

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[1] Subsection (b) of §360k provides a limited role for states to regulate medical devices, but only after obtaining the express authority to do so from the Secretary of Health & Human Services. The State of Maine did not seek such authority, nor was such authority granted with respect to the device at issue in this action.

medical devices into three classifications, based upon FDA's determination of the level of oversight needed to ensure the safety and effectiveness of the device. *See* 21 U.S.C. §360c(b)(1)(1994); 21 C.F.R. §860.84 (1995). Class I devices (*e.g.*, tongue depressors) require compliance solely with "general controls" established by the FDA, such as good manufacturing practices, to ensure safety and effectiveness. According to the MDA, Class I devices pose no unreasonable health risks and thus are subject to only minimal regulation designed to ensure that the labeling is accurate and that the product is safe when used as directed. *See* 21 U.S.C. §360c(a)(1)(A) (1994). Class II devices, such as the endoscope manufactured by Smith & Nephew and at issue in the present case, are devices for which the FDA has determined that general controls may be insufficient to provide reasonable assurance of safety and effectiveness. For Class II devices, manufacturers must comply not only with general controls but also with any applicable special controls that may be promulgated by the FDA, including performance standards, postmarket surveillance, patient registries, and the development and dissemination of guidelines. *Id.* §360c(a)(1)(B). Class III devices (*e.g.*, heart valves) are those devices which FDA has determined pose a potentially unreasonable risk of illness or injury or which are designed to be life-sustaining or life supporting. *Id.* §360c(a)(1)(C). In addition, until reclassified by the FDA, all devices on the market prior to the enactment of the MDA are automatically considered Class III devices. *Id.* §360c(f). (App. 21a).

As part of its complex regulatory scheme, the MDA established a series of three avenues through which FDA could review a medical device and approve it for use in the United States. *See* 21 U.S.C. §360c(i); §360e; §360j(g) (App. 22a). Those devices which a manufacturer intends to use for clinical research are approvable through the Investigational Device

Exemption ("IDE") regulations. 21 C.F.R. §§812.1 *et seq.* (1995). In order to obtain an IDE approval, a device manufacturer must submit information detailing the proposed experimental plan, the known safety and effectiveness data regarding the device, and information regarding the investigators who will be conducting the study. *Id.* The FDA reviews the submitted IDE material and, if appropriate, approves the IDE, allowing the manufacturer to distribute the device for use only in approved research studies. 21 U.S.C. §360j(g) (1994).

The second avenue for device review and approval is the premarket approval ("PMA") process. *Id.* §360e. Under the PMA process, a manufacturer must submit information, including clinical data, demonstrating to the satisfaction of the FDA that the device will be safe and effective if used consistent with its proposed labeling. *Id.*

The third avenue of device clearance, and the method of review at issue both in this case and the *Medtronic* action, is known as the "510(k) process" referring to the section of the MDA which established this method of approval. 21 U.S.C. §360(k) (App. 21a). Under the 510(k) process, FDA reviews a device to determine if it is "substantially equivalent" to an existing device or to a device introduced prior to the enactment of the MDA (collectively, "predicate devices"). 21 C.F.R. §807.81 (1995) (App. 25a).

Pursuant to the 510(k) process, device manufacturers must submit information including design and labeling information. Furthermore, FDA is authorized to request any additional information, including photographs, drawings or samples, necessary to determine whether the device is substantially equivalent to a predicate device. 21 C.F.R. §807.87 (1995) (App. 27a).

To determine that a device is substantially equivalent to a predicate device, a manufacturer is required to demonstrate that the device has the same intended use as the predicate device, and either that the device has the same technological characteristics as the predicate device or has different characteristics but does not raise any different questions of safety or effectiveness than the predicate device. 21 U.S.C. §360c(I)(i) (1994) (App. 22a).[2]

Once a device is cleared pursuant to Section 510(k), the FDA imposes significant requirements restricting any changes in device design. For example, a device cleared through the 510(k) process may not be changed in a manner that could affect its safety or effectiveness without the manufacturer seeking an additional 510(k) clearance by the FDA. 21 C.F.R. §807.81(A)(3)(i) (App. 25a). In addition, the FDA requirements for labeling and warnings on devices are identical for 510(k) devices as for devices approved through any other process such as the PMA. Furthermore, the MDA currently imposes strict requirements on post-market surveillance of all devices, including those cleared through the 510(k) process. The FDA is empowered to require device manufacturers to keep records and make reports of adverse reactions and serious injuries associated with use of the devices (21 U.S.C. §360i), to conduct post-market surveillance of devices (21 U.S.C. §360l), to notify the public of risks presented by the devices (21 U.S.C. §360(h)(a)), to repair or replace defective devices (21 U.S.C. §360h(b)), and to institute recall campaigns for defective devices (21 U.S.C. §360h(e)).

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[2] The 510(k) process is the same for all classes of medical devices. 21 C.F.R. 807.87, 807.92, 807.93 (1995).

The medical device at issue in this case consists of an endoscope with special knives and related equipment for use by surgeons in performing endoscopic procedures. The FDA classified this device as a Class II device pursuant to the MDA, 21 C.F.R. §888.1100, and cleared the device through the Section 510(k) process, finding that it was substantially equivalent to a predicate device (App. 31a). Pursuant to its 510(k) clearance and within the statutory framework of the FDCA, Smith & Nephew proceeded to market the device.

Because §360k(a) expressly provides that all state requirements which are "different from, or in addition to" any federal requirement and which "relate to the safety or effectiveness" of a medical device, allowing the action of a litigant to affect this regulatory scheme is contrary to the express intent of Congress and alters its comprehensive scheme to ensure the safety of the public while promoting technological innovation in the medical device industry.

B. Facts and District Court Proceedings

On December 22, 1993, respondent Russell Violette ("Violette") served Smith & Nephew with a complaint filed against it in Kennebec County Superior Court for the State of Maine. The complaint alleged negligence, breach of warranty and design defect regarding an endoscope manufactured by Smith & Nephew. Defendant removed the case to the United States District Court for the District of Maine pursuant to 28 U.S.C. §§1332 and 1441 on January 22, 1993 as a diversity of citizenship case with an amount in controversy in excess of $50,000 exclusive of interest and costs because respondent alleged serious physical injuries, medical expenses and lost income. After removing the case, Smith & Nephew answered respondent's complaint, raising federal preemption as a defense. Respondent waived his breach of warranty claim before trial, and in January of 1994, a trial was held on the

negligence and design defect claims. The jury returned a verdict in favor of respondent, awarding him $250,000 in damages. Judgment was entered in that amount on January 31, 1994, and after Smith & Nephew's motions for judgment notwithstanding the verdict and for a new trial were denied, a final amended judgment was entered on March 16, 1994 (App. 14a, 15a, 17a).

C. The Court of Appeals' Opinion

Following entry of the amended judgment, Smith & Nephew filed a timely notice of appeal to the United States Court of Appeals for the First Circuit, alleging, among other things, that the FDCA preempted respondent's state law liability claims.

The First Circuit held that Smith & Nephew had waived its preemption defense by raising it substantively for the first time only after trial (App. 4a). Citing the First Circuit's opinion in *Sweeney v. Westvaco Company*, 926 F.2d 29 (1st Cir.), *cert. denied*, 502 U.S. 899 (1991), the court held that because preemption of state law tort claims was not specifically pursued in the trial court, it could not be raised for the first time on appeal (App. 4a-7a). Specifically, the court of appeals noted that Smith & Nephew had pleaded preemption as a defense in its answer, but had neither developed the record on the issue nor pressed it in any fashion before the district court. The court, therefore, explicitly declined to address the potential applicability of federal preemption to this case (App. 4a).

In its appeal, Smith & Nephew relied on *International Longshoremen's Ass'n v. Davis*, 476 U.S. 380 (1986), where the Supreme Court held that Congress had deprived all courts of jurisdiction to decide certain cases involving conduct protected by the National Labor Relations Act ("NLRA"), and

therefore a plaintiff's state law claim was preempted despite defendant's failure to raise the issue until after the jury's verdict. The First Circuit, however, distinguished *Davis* as being based on a "choice of forum" rather than a "choice of law" question (App. 6a-7a). The First Circuit reasoned that under the NLRA, Congress had determined that the National Labor Relations Board would be the sole forum in which certain grievances would be addressed, while in the medical device field, Congress had only provided the type of law to be imposed on a manufacturer, not the forum in which that law could be applied. As a result, the Court determined that FDCA preemption did not deprive the court of jurisdiction, and was waived if not presented in a timely manner by a defendant (*Id.*).

In declining to follow this Court's decision in *Davis*, the First Circuit found that FDCA preemption was similar to the preemption at issue in *Sweeney v. Westvaco Co.*, 926 F. 2d 29 (1st Cir.), *cert. denied*, 502 U.S. 899 (1991), in which the court held that preemption under the Labor Management Relations Act ("LMRA") was not jurisdictional and could be waived. The First Circuit's holding in the current action, therefore, is that preemption under the FDCA is a question of choice of law, and thus is waivable if not asserted by a party in a timely manner.

REASONS FOR GRANTING THE WRIT

I. THE FIRST CIRCUIT COURT OF APPEALS DECISION CONFLICTS, IN PRINCIPLE, WITH SUPREME COURT DECISIONS, AS WELL AS DECISIONS OF THE FIRST CIRCUIT AND OTHER COURTS OF APPEALS.

The First Circuit's decision conflicts, in principle, with this Court's decision in *International Longshoremen's Ass'n v.*

Davis, 476 U.S. 380 (1986) which the First Circuit failed to apply to this action despite the strong similarities between Congressional intent for preemption under the NLRA and the MDA.

In *Davis*, a defendant union, having lost a trial on the merits, asserted that the plaintiff's claims were barred by the NLRA because they were brought in a court of law, and not before the NLRB. This Court found for the defendant, and held that preemption under the NLRA foreclosed all courts of jurisdiction to adjudicate certain claims, such that the defendant could assert it at any time, even after a trial on the merits. *Davis* at 398.

The First Circuit failed to recognize that the reasoning of the Supreme Court in *Davis* applies to preemption under the FDCA. The express Congressional decision to grant to FDA exclusive authority over medical device safety, effectiveness, review and approval closely parallels its intent to grant to the NLRB sole authority to hear certain actions arising under the NLRA. As this Court stated in *Davis*:

> Congress evidently considered that centralized administration of specially designed procedures was necessary to obtain uniform application of its substantive rules and to avoid these diversities and conflicts likely to result from a variety of local procedures and attitudes toward labor controversies ... A multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law.

Davis at 389, *citing Garner v. Teamsters*, 346 U.S. 485, 490-91 (1953). In enacting the NLRA, Congress chose the NLRB as the forum in which to consider certain actions. By selecting

this forum, Congress extinguished any state jurisdiction over those same issues, thus preempting a state's adjudicatory power. *Davis* at 391.

In finding that preemption under the NLRA was jurisdictional, the *Davis* Court reasoned that Congress intended to grant primary interpretation of the NLRA to a specific and specially constituted body operating under a particular set of procedures, including investigation, notice, hearing and judicial relief pending a final administrative order. *Davis* at 389.

In enacting §360k, Congress made a similar determination that FDA would be given sole responsibility to consider and decide issues regarding the safety and effectiveness of medical devices, thereby helping to ensure the public's health and safety. S. Rep. No. 33, 94th Cong., 2d Sess. 2, *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. Similarly, Congress was aware of the need to provide a single, national set of uniform standards in order to assure both that the public's health would be protected and that innovations in medical device technology would not be stifled by unnecessary and discordant restrictions. H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976). By placing sole review of device safety and effectiveness with the FDA, Congress sought to guarantee that decisions would be made by experts competent to understand the complex technical and medical issues which often surround medical device design. Finally, as with the NLRA, the MDA and the regulations promulgated thereunder provide a complete procedural framework, including investigations, notices, hearings, as well as appeals and judicial relief if necessary. *See* 21 U.S.C. §§360d, 360e, 360g. By not realizing the extent of similarity between NLRA and FDCA preemption, the First Circuit erred in not applying a *Davis* preemption analysis to the present action. If it had done so, the court would have

recognized the jurisdictional nature of preemption under the FDCA.

Several Circuit decisions support petitioners' contention that Congress granted to the FDA exclusive authority to review the safety and effectiveness of medical devices. *See, e.g., Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir. 1994) ("Congress enacted the MDA to give the [FDA] comprehensive control over medical devices for the first time."); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 395 (4th Cir. 1995) *petition for cert. filed*, 64 U.S.C.W. (Dec. 22, 1995) (No. 95-1010) ("Congress established a scheme for comprehensive regulation of medical devices ..."); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1331 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992).

In a recent decision, the First Circuit, in apparent self-contradiction with the present action, demonstrated the extent to which the FDCA preempts court actions against a device manufacturer. *See Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995). In *Talbott*, the First Circuit held that plaintiffs' numerous tort claims, including negligence, breach of express and implied warranties, fraudulent misrepresentation, civil conspiracy, and unfair trade practices, were all preempted by the FDCA.[3] The Court's analysis of the MDA in *Talbott* makes clear that the scope of preemption is so extensive as to be jurisdictional in nature. The *Talbott* court states:

> To avoid the possibility of disuniform treatment, Congress placed enforcement authority in the FDA.... Centrally situated and with the requisite expertise, the

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[3] The defendant in *Talbott* had previously plead guilty to a criminal indictment of conspiring to defraud the FDA by intentionally submitting false information to the agency.

> FDA is in the best position to determine whether the provisions of the MDA have in fact been violated and to ensure that the law is applied in a uniform manner.

Talbott at 29-30. The opinion further stresses that:

> The public interest will best be served by relying exclusively on the FDA to strike the proper balance between reasonably assuring safety and promoting innovation with regard to new devices that have the potential both to enhance and injure human health.

Id. As a result, the First Circuit held that all of plaintiff's claims are preempted, without exception. *Id.* at 29; *see also Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994) ("Congress's intent in enacting [the FDCA preemption] provision was to prevent state requirements from unduly burdening interstate commerce."); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541 (3rd Cir.) *cert. denied*, 115 S. Ct. 429 (1994) ("the MDA also limits entities other than the FDA from imposing requirements on the makers of medical devices and the process by which those devices are discovered, investigated and manufactured."); S. Rep. No. 33, 94th Cong., 2d Sess. 5, 12 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1074, 1081). Thus, preemption under the MDA is a question of choice-of-forum rather than choice-of-law, because Congress designated the FDA as the sole forum to address issues as to the safety and effectiveness of medical devices.

Several other circuits have similarly held that Congress intended the FDCA preemption provision to be broadly applied to court claims. In *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995), the Fifth Circuit preempted a plaintiff's failure to warn claim, finding that the FDCA was designed to "establish an extensive enforcement scheme under which the FDA bears primary responsibility for

policing violations of its regulations." *Reeves* at 307. The *Reeves* court recognized that permitting a failure to warn claim against a device manufacturer would "constitute a collateral attack on the FDA's original determination that a manufacturer was in compliance with all applicable regulations." *Reeves* at 307. *See also National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994) (preempting plaintiff's failure to warn claim despite allegations that manufacturer failed to comply with FDA regulations).

The Third Circuit has likewise reasoned that the FDA has exclusive authority to determine the safety and efficacy of a medical device and that claims of fraud on the FDA were preempted. *See Michael v. Shiley, Inc.*, 46 F. 3d 1316 (3rd Cir.), *cert. denied*, 116 S. Ct. 67 (1995). In *Michael*, the Third Circuit found that "where the FDA renders the expert decision, ... it, and not some jury or judge, is best suited to determine the factual issues and what their affect would have been on its original conclusions. *Michael* at 1329, *citing King v. Collagen Corp.*, 983 F.2d 1130, 1140 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) (Aldrich & Campbell, J.J. concurring). If a manufacturer misleads the FDA, it is the FDA's function to remedy the situation using the authority Congress gave it in the MDA. *Michael* at 1329.

The reasoning of these courts demonstrates the extent of the authority Congress delegated to the FDA over medical device review. As intended by Congress, the MDA preemption provision gave the FDA exclusive authority to determine the safety and effectiveness of medical devices. The First Circuit's ruling in the present action fails to recognize this Congressional determination. According to the First Circuit, private litigants, through their use of the courts, may do what Congress has forbidden the states and political subdivisions from doing, namely, imposing different and additional requirements on

medical devices. In essence, parties in a civil action can cause a court to re-evaluate the adequacy of FDA decisions regarding the safety and effectiveness of a device, thus frustrating the specific and express intention of Congress to place these issues solely before the FDA.

This Court should reconcile the conflicting approach taken by the First Circuit in the present action with the clear intent of Congress in enacting §360k of the MDA, and, as in *Davis*, find that medical device preemption under the MDA is jurisdictional.

II. THE CASE PRESENTS AN IMPORTANT FEDERAL QUESTION WHICH SHOULD BE SETTLED BY THIS COURT, PARTICULARLY IN LIGHT OF THIS COURT'S GRANT OF CERTIORARI IN MEDTRONIC, INC. V. LOHR.

On January 19, 1996, this Court granted certiorari in *Medtronic, Inc. v. Lohr*, Nos. 95-754 and 95-886, to review a decision from the Eleventh Circuit. (*Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995)). The issue under review in *Medtronic* is whether §360k(a) of the FDCA preempts state common law claims that would expose a manufacturer to liability for a device design that was reviewed and cleared by the FDA. This petition asks this Court to consider the next logical question: whether preemption under §360k(a) of the FDCA provides the FDA with sole authority to consider the safety and effectiveness of medical devices, thereby extinguishing the jurisdiction of courts over these same issues? Therefore, granting this petition and reviewing both issues simultaneously would be appropriate.

The similarity of circumstances in these two cases warrant their simultaneous consideration. Both the device at

issue in *Medtronic* and in this action were cleared for marketing through the 510(k) premarket notification process. Similarly, both cases involved allegations that the devices were designed improperly and had allegedly insufficient warnings. Therefore, together with *Medtronic*, the present case provides the opportunity for this Court to address, for the first time, the extent of federal preemption under the FDCA with regard to medical devices cleared through the 510(k) process, as well as the nature of that preemption.

Currently, there is significant inconsistency among the federal circuits regarding the scope and nature of medical device preemption.[4] A decision of this Court would have wide ranging implications on the medical device industry because 98% of reviewed medical devices enter the market through the 510(k) premarket notification process. H.R. Rep. No. 808, at 14, *reprinted in* 1990 U.S.C. C.A.N. 6307. Under the FDCA, the review process for 510(k) devices focuses not on particular pre-existing design standards, but rather on a determination of substantial equivalence of design and function and on the process itself.

This Court's forthcoming consideration of preemption in the *Medtronic* case will inevitably affect the present action. Any decision by this Court will define the limits of federal preemption under the FDCA, and therefore, will directly impact on whether or not federal preemption of medical devices is jurisdictional in nature. In the interests of developing a consistent and reasoned approach to medical

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[4] Compare, *e.g.*, *Gile*, 22 F.3d 540 (3rd Cir.), *cert. denied*, 115 S. Ct. 429 (1994) (finding and discussing broad preemption of state tort claims) with *National Bank of Commerce*, 38 F.3d 988 (8th Cir. 1994) (declining to find preemption of a design claim for a Class II 510(k) device).

device preemption, this Court should grant this petition, and decide the issues raised in this action together with those before this Court in the *Medtronic* petition.

CONCLUSION

For the above and foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

SMITH & NEPHEW DYONICS

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Dated February 26, 1996

APPENDIX A - OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT DATED AUGUST 7, 1995

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 94-1291

RUSSELL VIOLETTE,
Plaintiff - Appellee,
V.
SMITH & NEPHEW DYONICS, INC.,
Defendant - Appellant.

No. 94-1334

RUSSELL VIOLETTE,
Plaintiff - Appellant,
V.
SMITH & NEPHEW DYONICS, INC.,
Defendant - Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Eugene W. Beaulieu, U.S. Magistrate Judge]

Before

Boudin, Circuit Judge,
Aldrich, Senior Circuit Judge,
and Young, District Judge.[1]

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[1] Of the District of Massachusetts, sitting by designation.

Joseph J. Leghorn, with whom Peter T. Wechsler, Warner & Stackpole, Edward W. Gould and Gross, Minsky, Mogul & Singal, P.A., were on brief for appellant Smith & Nephew Dyonics, Inc.

Daniel J. Popeo and Richard A. Samp on brief for Washington Legal Foundation and Allied Educational Foundation, amici curiae.

Randall E. Smith, with whom John H. O'Neil, Jr., Smith, Elliott, Smith & Garney, P.A., were on brief for appellee Russell Violette.

Jeffrey R. White on brief for the Association of Trial Lawyers of America, amicus curiae.

August 7, 1995

YOUNG, District judge. Russell Violette ("Violette") Instituted this action in the Superior Court in and for Kennebec County, Maine, seeking to recover for damage to his left wrist allegedly caused by the improper use of a medical device manufactured by the defendant Smith & Nephew Dyonics, Inc. ("Dyonics"), a Massachusetts corporation. Dyonics removed to federal court, where Violette ultimately obtained a jury verdict in the amount of $250,000. Dyonics' appeal duly followed. It must fail.

The relevant prior proceedings and the facts supporting the jury's verdict, see Data General Corp. v. Grumman Sys. Support Corp., 36 F.3d 1147, 1172 (lst Cir. 1994), may be sketched briefly. In the summer of 1991, Violette experienced numbness in his hands and consulted Dr. Robert C.G. Hottentot, an orthopedic surgeon. Dr. Hottentot's diagnosis was carpal tunnel syndrome, and Violette underwent a relatively new surgical "endoscopic" procedure involving the

insertion of a slotted metal tube with a camera lens into the carpal tunnel running from the patient's wrist to his palm- The surgeon employed the technique developed and equipment manufactured by Dyonics known as the ECTRA System (the "product") which consists of an endoscope and a set of related devices specifically designed for endoscopic carpal ligament release. The outcome of the surgery was not as doctor and patient had hoped -Violette's ulnar nerve and artery were severed, resulting in permanent injury to the nerve which left his small and ring fingers curled up into the shape of a claw.

Violette's tort action against Dyonics alleged negligence (primarily failure to warn) , design defect, and breach of warranty. In its post-removal Answer, Dyonics asserted four affirmative defenses: 1) the product was designed and manufactured using techniques representing the state of the art at the time it was manufactured and sold; 2) any harm to Violette was caused entirely by the fault of third parties for which Dyonics cannot be held liable; 3) Dyonics provided adequate instructions and warnings regarding the appropriate use of the product; and 4) "Federal regulation of the subject product preempts the present action."

With the parties' consent, the case proceeded to trial before a United States Magistrate Judge on the failure to warn and design defect theories, Violette having waived his breach of warranty claim. At the close of Violette's evidence, Dyonics moved for directed verdict, which was denied. 2k renewed motion for directed verdict, made at the end of the defense case, and a motion for judgment notwithstanding the verdict or for new trial, made after the jury came back in Violette's favor, met with a similar fate. Other than asserting federal preemption in its answer, Dyonics never mentioned it again either before or during the trial. It surfaced as an allegedly viable issue only after the jury returned its verdict.

A. Preemption

The thrust of Dyonics' appeal is that provisions of the Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C.A. §§301 *et seq.* (West 1972 Supp. 1993), preempt Violette's state-law products liability claims. Specifically, Dyonics points to the Medical Device Amendments of 1976, 21 U.S.C.A. §§351-60 (West Supp. 1993), as barring the claims made in this case.[2] See generally Gail H. Javitt, *I've Got You Under My Skin -- And I Can't: Get Redress: An-Analysis of Manufacturer Liability for Class III Medical Devices*, 49 Food and Drug L.J. 553 (1994). It is simply too late, however, for Dyonics to make this argument. Regardless of its potential applicability, and we express no opinion on the subject, Dyonics has waived the preemption issue by raising it substantively for the first time after trial.

The question of waiver is controlled by a recent decision of this court, Sweeney v. Westvaco Co., 926 F.2d 29, 36-41 (lst Cir.), cert. denied, 502 U.S. 899 (1991). In Sweeney, we held that the defendant waived its preemption defense by waiting to raise it until after the jury had returned an adverse verdict. Id. at 37. Westvaco's failure to "alert the court to the

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[2] The amendment states in part:

[N]o state . . . may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device . . .

21 U.S.C. §§360k(a) (West Supp. 1993)

problem" at any one of myriad opportunities prior to the jury verdict led us to decline to consider the defense.

So here. An issue not presented to the trial court may not be raised for the first time on appeal. G.D. v. Westmoreland School Dist., 930 F.2d 942, 950 (lst Cir. 1991) (plaintiff cannot raise on appeal issue not articulated below) ; Wallace Motor Sales, Inc. v. American Motor Sales Corp., 780 F.2d 1049, 1067 (lst Cir. 1985). Although Dyonics pleaded preemption as an affirmative defense in its answer, it neither developed a record on the issue nor pressed it in any fashion before the district court. Merely mentioning an issue in a pleading is insufficient to carry a party's burden actually to present a claim or defense to the district court before arguing the matter on appeal. Cookish v. Cunningham, 787 F.2d 1, 6 (1st Cir. 1986) (per curiam) (allegation in pleadings insufficient to preserve issue on appeal); Bratt v. International Business Machines Corp., 785 F.2d 352, 362 n.1 (1st Cir. 1986) (breach of confidentiality claim mentioned in complaint but never pressed deemed waived); Wallace Motor Sales, 780 F.2d at 1067 (1st Cir. 1985) (issue raised in pleadings but not at trial was not "presented" to district court and could not be argued on appeal) (citing In re Linda Coal and Supply Co. v. L.H. Haberman and Son, 255 F.2d 653 [3d Cir. 1958]).

Dyonics had ample opportunity and incentive to assert preemption below. It chose, however, neither to file a motion to dismiss nor to press for summary judgment on the issue. In its Pretrial memorandum, under the headings "Facts and Defenses" and "Controverted Points of Law," Dyonics asserted only that the endoscopic carpal tunnel surgery was an "accepted practice"; that it warned physicians, including Dr. Hottentot, of the possibility of injury such as that incurred by Violette; and

that Violette's claim was barred by the "learned intermediary" defense. There is no mention of preemption. Nor did Dyonics assert preemption in its trial brief, its numerous motions in limine, its two motions for directed verdict, and its motion for judgment n.o.v. or for new trial. See Sweeney, 926 F.2d at 38. For whatever reason, it is plain that preemption flickered but once, dimly, on the radar screen of this litigation and then disappeared forever, abandoned by Dyonics, depriving the magistrate judge of his rightful opportunity to address the question in the first instance. To allow Dyonics to resurrect the issue here would undermine the logic behind our refusal to consider issues not presented below: Dyonics "cannot evade the scrutiny of the district court . . . on appeal with a new claim in order to create essentially a new trial." Westmoreland School District, 930 F.2d at 950. Since this is precisely what Dyonics is attempting, and as there are no exceptional or particular circumstances requiring a detour from the traditional rule, see *id.*, the applicability of federal preemption is deemed waived and we will not examine its applicability to this case.

No doubt recognizing the apparent applicability of Sweeney v. Westvaco to the facts of this case, Dyonics argues that, in the present circumstances, preemption is a jurisdictional matter which cannot be waived and may be raised at any time. It relies primarily on International Longshoremen's Ass'n v. Davis, 476 U.S.380 (1986), where the Supreme Court held that Congress had deprived the courts of jurisdiction to decide cases involving conduct arguably protected by the National Labor Relations Act, and thus that the plaintiff's state-law fraud claim was preempted despite the defendant's failure to raise the issue until after the jury's verdict. See id. at 398; see also Sweeney, 926 F.2d at 37-38. In Sweeney, however, we pointed out that the Davis principle stemmed from federal statutes involving a "choice-of-forum rather than a choice-of-law question." Sweeney, 926 F.2d at 38 (quoting Davis, 476 U.S. at 391 &

n.9). That is, where Congress has designated another forum for the resolution of a certain class of disputes, such as the National Labor Relations Board in Davis, such designation deprives the courts of jurisdiction to decide those cases. See Sweeney, 926 F.2d at 37. Where, however, the question is whether state tort or federal statutory law controls, preemption is not jurisdictional and is subject to the ordinary rules of appellate adjudication, including timely presentment and waiver. See id. at 39. This case presents a "choice-of-law" question and thus falls squarely within the latter category. Preemption is not here jurisdictional, and was waived when not presented in the district court.[3]

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[3] None of Dyonics' proffered authority addresses the question of waiver of the preemption issue on appeal. See Kennan v. Dow Chemical Co., 717 F. Supp. 799 (M.D. Fla. 1989); Fitzgerald v. Mallinckrodt, Inc., 681 F. Supp. 404 (E.D. Mich. 1987); Ignace v. International Playtex, Inc., No. 86-C-480-C, 1987 WL 93996 (W.D. Wis. Aug. 14, 1987). In each of those cases, the defendants were permitted to raise the preemption issue for the first time in the context of summary judgment -- an unremarkable result given the liberal standard for amendments to pleadings of Fed. R. Civ. P. 15(c). As the time for amending pleadings has long passed here, these cases are inapposite.

Nor is a recent case of ours, Mendes v. Medtronic, Inc., 18 F. 3d 13 (1st Cir. 1994), of any assistance to Dyonics. Affirming a grant of summary judgment to the defendant, we held there that the Medical Device Amendments, 21 U.S.C. §360k, preempted plaintiff's common law negligent failure to warn claim against a pacemaker manufacturer because a factfinder could impose liability on such a claim "applying standards differing from or adding to FDA's." Id. at 19. The language of the statute and its application in Mendes leave open the possibility that a state may impose, establish, or continue burdens identical to the federal standards, leading ineluctably to the conclusion that the statute's preemptive effect is not jurisdictional. Had Dyonics brought its preemption argument

B. The Jury Verdict

Violette claimed generally that the ECTRA System was "in a defective condition unreasonably dangerous," and that Dyonics failed to warn of the dangers associated with its product. Dyonics asserts that as matter of law its product was free from defect; that its product was unavoidably unsafe and is therefore exempt from strict liability; that Dyonics fulfilled its duty to warn; that Dyonics cannot be liable for a surgeon's selection of a particular Procedure; and that Violette failed to prove the product proximately caused his injuries. Dyonics also urges that we reverse because the magistrate judge declined to give certain jury instructions. These arguments reflect more hope than experience.

Maine law provides:

> One who sells any goods or products in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to a person whom the manufacturer,

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before the district court at the proper time, like the Mendes plaintiff, this Court could have reached the merits. The supplemental authorities provided by Dyonics -- recent cases in which district courts have held that the Medical Device Amendments preempt state tort claims -- merely serve to highlight the proper procedural context in which preemption claims ought first be litigated. See Committee of Dental Amalgram Alloy Mfrs. v. Henry, 871 F. Supp. 1278, 1285 (S.D. Cal. 1994) (holding on motion to dismiss the wrongful death and other state-law causes of action preempted by section 360(k)(appeal pending); Feldt v. Mentor Corp., No. H-93-2205. slip op. at 1-2, 10 (S.D. Tex. July 11, 1994)(holding on summary judgment that negligence and product liability claims preempted by Medical Devices Amendments and FDA regulations).

> seller or supplier might reasonably have expected to use, consume or be affected by the goods, or to his property, if the seller is engaged in the business of selling such a product and it is expected to and does reach the user or consumer without significant change in the condition in which it is sold. This section applies although the seller has exercised all possible care in the preparation and sale of his product and the user or consumer has not bought the product from or entered into any contractual relation with the seller.

ME. REV. STAT. ANN. tit. 14, §221 (West 1980).

Maine applies the danger/utility test to claims of design defects -- that is, the finder of fact must weigh the utility of the product against the danger it presents. Quiggey v. Bombardier, 615 A.2d 1169, 1172 (Me. 1992) ; St. Germain v. Husquanna Corp., 544 A.2d 1283, 1285 (Me. 1988) ; Stanley v. Schiavi Mobile Homes, Inc., 462 A.2d 1144, 1148 (Me. 1983); Porter v. Pfizer Hosp. Prod. Group, Inc., 783 F. Supp. 1466, 1474 (D. Me. 1992) (plaintiff cannot prevail on defective design claim where he introduced no evidence that the utility of the design was outweighed by the risks). This process involves an examination of utility, risk, and the feasibility of safer alternatives. St. Germain, 544 A.2d at 1285 (quoting Stanley, 462 A.2d at 1148) . The jury's determination that the product was not safely designed to carry out its intended use was supported by the evidence, and therefore must stand.

Dr. Morton Kasdan testified that the product here was defectively designed because it required only approximations in the initial placement of the tube on the outside of the skin

without being able to see the ulnar nerve and artery, and that when inserted below the carpal ligament, the knife cuts through the ligament before the surgeon can see what is above the ligament. Dr.- Kasdan also testified that the risk involved was enormous and that the product's use provided no benefit beyond those available with the safer, proven, alternative technique of open carpal tunnel surgery Dyonics' own expert admitted that he had participated in the development of an alternative "extrabursal" technique which sought to minimize the risks by moving the initial placement point and the cutting line further from the ulnar nerve. Given such testimony, there was sufficient competent evidence for the jury to believe and conclude that the ECTRA System was unreasonably dangerous and of little added utility compared to available alternatives -- in short, defectively designed.[4]

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[4] Likewise, the evidence of an alternative safe method of surgery defeats Dyonics' claim that its product is unavoidably unsafe and therefore exempt from strict liability under comment k of section 402A of the Restatement (Second) of Torts, which requires a showing that the utility or benefit of the product outweighs its risk of danger. See Kearl v. Lederle Lab. , 218 Cal. Rptr. 453, 464 (Ct. App. 1985) (court must consider availability and safety of alternative products) ; Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118, 123 (Colo. 1983) (en banc) (manufacturer must demonstrate that the "product's benefits could not be achieved by a substitute product or in another manner") ; Toner v. Lederle Lab., 732 P.2d 297, 306 (Idaho 1987) (additional element of comment k's requirement of unavoidable risk is that there must be "no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk") ; Grundberg v. Upjohn Co. , 813 P.2d 89, 93 (Utah 1991) (same) . Even if comment k accurately reflects Maine common law -- a point we need not decide and express no opinion thereon -- the refusal of the magistrate judge to find the product avoidably unsafe and exempt from strict liability was not clear error. Salve Regina College v. Russell, 499 U.S. 225, 233 (1990) (mixed questions of fact and law are reviewed for clear

The jury's determination that Dyonics failed to provide adequate warnings and directions is likewise supported by the evidence. A manufacturer must provide expected users of its product with warnings of the risks and "specific directions for the product's safe use." Pottle v. Up-Right, Inc., 628 A.2d 672, 675 (Me. 1993) . While the Supreme Judicial Court of Maine has not decided the matter, the general rule regarding medical devices (and, more frequently and by analogy, prescription drugs) is that the manufacturer must warn the physician -- the so-called "learned intermediary -- and not the patient directly. See Knowlton v. Deseret- Medical, Inc. , 930 F.2d 116, 120 n.2 (lst Cir. 1991) (in failure-to-warn suit against catheter manufacturer, we noted that it "is generally accepted that in a case involving medical products prescribed or used by a physician or trained medical personnel, the warning runs to the physician not the patient"); Phelps v. Sherwood Medical Indus., 836 F.2d 296, 299, 302 (7th Cir. 1987) (heart catheter manufacturer has duty to warn physicians); Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) (pace-maker manufacturer has duty to warn physician, not patient) ; Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 17 & n.5 (D. Conn. 1989) (manufacturer of breast implants has duty to warn physician); cf. Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992) (where product is a prescription drug, duty to warn runs to physician). Dr. Chow, Dyonics' ECTRA System instructor, admitted that in May of 1991, when the equipment was Purchased by Dr. Hottentot's practice, the extrabursal technique was being taught at seminars put on by the ECTRA faculty. Both Dr. Chow and Jan Cook, the associate product manager for Dyonics, admitted that the extrabursal technique

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error; "deferential review" warranted when district court "better positioned" to decide the issue) ; Touch v. Master Unit Die Prods., Inc., 43 F. 3d 754, 757 (lst Cir. 1995) ; ICC v. Holmes Transp., Inc., 983 F.2d 1122, 1128 (lst Cir. 1993).

was safer and easier to learn and to teach. Dr. Hottentot was not provided with any materials referring to this safer technique or given adequate warnings of the real potential for complications. On this record, we conclude that the jury had sufficient basis to find Dyonics in breach of its duty to warn.

Dyonics argues that a failure to warn claim will not lie under Maine law where the risk of danger associated with the use of the product was obvious to the user, citing Lorfano v. Dura Stone Steps, Inc., 569 A.2d 195, 197 (Me. 1990) ("dangers posed by the use of steps without a handrail are patently obvious and equally apparent to all"). A high-technology, precision medical device is, needless to say, a far cry from a handrail. Moreover, while a physician cannot be held liable for an adverse outcome simply because the result could have been avoided by a different selection as between two reasonable procedures, Roberts v. Tardif, 417 A.2d 444, 448 (Me. 1980), here there was sufficient evidence that use of the ECTRA System was unreasonably dangerous without further warnings or proper instructional materials. A jury could conclude that Dr. Hottentot's uninformed choice of the product was not a reasonable selection of an alternative surgical procedure, thus insulating Dyonics from liability. Any extension of Roberts to protect a manufacturer in Dyonics' position is unwarranted.

A jury verdict may be set aside "only if [it] is so seriously mistaken, so clearly against the law or the evidence, as to constitute a miscarriage of justice." Levesque v. Anchor Motor Freight, Inc., 832 F.2d 702, 703 (lst Cir. 1987). Such is not the case here.

Finally, the magistrate judge committed no error by refusing to give two proposed jury instructions. Dyonics sought an instruction, based on Roberts, supra, that a

manufacturer of a medical device cannot be held liable merely because the surgeon could have pursued an alternate course of treatment and thereby avoided the injury. As noted above, such an extension of Roberts is unwarranted in this case. Dyonics also sought the following instruction, citing May v. Dafoe, 611 P.2d 1275, 1278 (Wash. App.-1980):

> A manufacturer of medical products is not responsible for the education and training of doctors who may use its product. The responsibility for determining whether an individual doctor is sufficiently skilled and trained to use a particular product lies with the doctor himself or herself and the facilities where they practice.

Such instruction was unnecessary in this failure to warn design defect case and, in any event, the refusal to give this instruction caused no prejudice to Dyonics since Dr. Hottentot followed the product instructions he had been given. See Davet v. Maccarone, 973 F.2d 22, 26 (lst Cir. 1992) ("An error in jury instructions will warrant reversal of a judgment only if the error is determined to have been prejudicial, based on a review of the record as a whole").

For these reasons, the Amended Judgment entered in this action on March 17, 1994, pursuant to the jury's verdict, is affirmed.[5]

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[5] Violette also cross-appealed, requesting reversal of numerous rulings of the magistrate judge in the event we had determined that Dyonics was entitled to a new trial. As Dyonics is not so entitled, there is no need to address the issues raised by the cross-appeal, and it is dismissed as moot.

APPENDIX B - JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE DATED JANUARY 31, 1994

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

RUSSELL VIOLETTE,	)	
	)	
Plaintiff	)	
	)	
VS.	)	Civil No. 93-16-B
	)	
SMITH & NEPHEW	)	
	)	
Defendant	)	

JUDGMENT

This matter having come before the Court, Honorable Eugene W. Beaulieu presiding, and the issues having been duly tried, and pursuant to the verdict of the jury,

JUDGMENT is hereby entered for the plaintiff, and against the defendant in the amount of Two Hundred Fifty Thousand Dollars ($250,000.00).

Dated at Bangor, Maine this 31st day of January, 1994.

WILLIAM S. BROWNELL,
CLERK

By: _____

Brenda Thomas
Deputy Clerk

APPENDIX C - ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE DATED FEBRUARY 17, 1994

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

RUSSELL VIOLETTE,	)	
	)	
Plaintiff	)	
	)	
VS.	)	Civil No. 93-0016-B
	)	
SMITH & NEPHEW DYONICS, INC.,	)	
	)	
	)	
Defendant	)	

ORDER

This cause was tried to a jury beginning on January 24, 1994. On January 27, 1994 the jury returned a verdict in favor of Plaintiff. Defendant has moved for Judgment N.O.V. or for a new trial pursuant to Federal Rules of Civil Procedure 50 and 59. The Court has carefully considered the arguments in support of, and opposition to, the Motion. Accordingly, Defendant's Motion For Judgment N.O.V. Or For New Trial is DENIED.

SO ORDERED.

Dated at Bangor, Maine this 17th day of February, 1994.

Appendix C

Eugene W. Beaulieu
United States Magistrate Judge

APPENDIX D - AMENDED JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE DATED MARCH 16, 1994

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

RUSSELL VIOLETTE	)	
	)	
Plaintiffs	)	
	)	
VS.	)	Civil No. 93-16-B
	)	
SMITH & NEPHEW	)	
	)	
Defendant	)	

AMENDED JUDGMENT

This matter having come before the Court, Honorable Eugene W. Beaulieu presiding, and the issues having been duly tried, and pursuant to the verdict of the jury, and pursuant to the order of Court dated February 17, 1994,

JUDGMENT is hereby entered for the plaintiff and against the defendant in the amount of Two Hundred Fifty Thousand Dollars ($250,000.00).

Dated at Bangor, Maine, this 16th day of March, 1994

Brenda Thomas,
Deputy Clerk

APPENDIX E - ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT DENYING PETITION FOR REHEARING AND THE SUGGESTION FOR REHEARING EN BANC DATED NOVEMBER 29, 1995

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 94-1291

RUSSELL VIOLETTE,
Plaintiff, Appellee,
V.
SMITH & NEPHEW DYONICS, INC.,
Defendant, Appellant.

No. 94-1334

RUSSELL VIOLETTE,
Plaintiff, Appellant,
V.
SMITH & NEPHEW DYONICS, INC.,
Defendant, Appellee.

Before
Torruella, Chief Judge,
Aldrich, Senior Circuit Judge,
Selya, Cyr, Boudin, Stahl and Lynch, Circuit Judge
and Young,* District Judge.

ORDER OF COURT
Entered: November 29, 1995

The panel of judges that rendered the decision in these cases having voted to deny the petition for rehearing and the suggestion for the holding of a rehearing en banc having been

carefully considered by the judges of this Court in regular active service and a majority of said judges not having voted to order that the appeals be heard or reheard by the Court en banc,

It is ordered that the petition for rehearing and the suggestion for rehearing en banc be denied.

By the Court:

Clerk.

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*Of the District of Massachusetts, sitting by designation.

APPENDIX F - STATUTORY AND REGULATORY PROVISIONS

21 U.S.C.§360(k)

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe)--

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

(As amended Aug. 16, 1972, Pub.L. 92-387, §§ 3, 4(a)-(c), 86 Stat. 560-562; May 28, 1976, Pub.L. 94-295, § 4(a), 90 Stat. 579.)

21 U.S.C. §360c(f)(1)

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless--

(A) the device--

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the

Secretary under paragraph (2) classifying the device in class I or II.

21 U.S.C. §360c(i)

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device--

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(June 25, 1938, c. 675, § 513, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 540, and amended Nov. 28, 1990, Pub.L. 101-629, §§ 4(a), 5(a), (b), (c)(1), (c)(3), 12(a), 18(a), 104 Stat. 4515, 4517, 4518, 4523, 4528; June 16, 1992, Pub.L. 102-300, § 6(e), 106 Stat. 240; Aug. 13, 1993, Pub.L. 103-80, § 3(s), 107 Stat. 778.)

21 U.S.C. § 360k

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

(1) the requirement is more stringent than a requirement under this chapter which would be

applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement--

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, c. 675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574.)

21 C.F.R. § 807.81

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device

in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b) A premarket notification under this subpart is not required for a device for which a premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of Part 1002 of this chapter.

21 C.F.R. § 807.87

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change of modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(k) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0281)

[42 FR 42526, Aug. 23, 1977, as amended at 57 FR 18066, Apr. 28, 1992; 59 FR 64295, Dec. 14, 1994]

21 C.F.R. § 808.1(d) (Excerpt)

§ 808.1 Scope.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific

requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 888.1100

§ 888.1100 Arthroscope.

(a) Identification. An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.

(b) Classification. Class II.